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10/612,784	07/02/2003	Ray C. Wasielewski	ORW01-GN004	5434

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EXAMINER	
SNOW, BRUCE EDWARD	
ART UNIT	**PAPER NUMBER**
3738	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/612,784	WASIELEWSKI, RAY C.	
	Examiner	Art Unit	
	Bruce E. Snow	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-6,14,15,27-32,37-39 and 109* is/are pending in the application.

4a) Of the above claim(s) *38 and 39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-6,14,15,27-32,37 and 109* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 10/11/07 have been fully considered. Applicant arguments begin:

> Rebuttal of Examiner's Response to Applicant's Arguments
> Applicant takes exception with the conclusory rationale recited in the two most recent Office actions for rejecting those pending claims. It is the Examiner's responsibility to "provide clear explanations of all actions taken by the examiner during prosecution of an application."1 Because Applicant traversed the prior art rejections, the Examiner is required to "answer the substance of [those arguments]." 2 Replying with an improper standard of "one of ordinary skill" as to the sufficiency of a conclusory explanation satisfies neither of those requirements. The Examiner has a duty under M.P.E.P. § 707.07(f) to provide substantive explanation of the rejections of record. The mere conclusions offered by the Examiner do not further prosecution and certainly fail to provide Applicant and the Board of Appeals with sufficient facts upon which to assess the grounds of rejection.

"The conclusory rationale" and "t*hose pending claims*" are ambiguous. In future responses, please be specific regarding the subject of your arguments.

Regarding the rejection of at least claim 1 under 35 U.S.C. 112, second paragraph, "*wherein the augment material is formulated not to transform into scar tissue"* is still ambiguous. The paragraph before claims, "*wherein the augment material is supplemented with at least one of an agent to promote the formation of scar tissue*". So the material does not transform into scar tissue but contains an agent to promote scar tissue?

Regarding the rejection under 35 U.S.C. 112, first paragraph, applicant quotes the specification for support:

> [0040] In the exemplary embodiment utilizing the biologically reabsorbable snap- on augments 26, such augments 26 could be formulated to absorbed over a relatively short period (i.e., several weeks or months) and could also be formulated so as to be replaced by tissue (such as scar-tissue) that would

provide for long-term hip stability and, hopefully, normal motion. Such formulations of biologic materials are well known by those of ordinary skill in the art

It is the Examiner's position that the augments "could also be formulated so as to be replaced by tissue (such as scar-tissue)" does not inherently conclude the exact opposite "*wherein the augment material is formulated not to transform into scar tissue*".

Regarding the rejections including the Kuber reference, it is the Examiner's strong position that Kuber's teaching "the resorbable luxation retaining ring.. is suitable for **all common commercial hip prosthesis socket components** and **socket inlays** made of plastic (see abstract)", Kuber refers to the liner as an inlay, teaching a typical liner and cup configuration; applicant claiming a liner and cup is not inventive but simply well known. The Examiner includes a combination rejection including Mikhail further teaching this.

Regarding the new limitation, "*wherein the augment is formulated not to transform into scar tissue*", the Examiner truly does not know what to make of this. Why would applicant's device made of the same PLLA (see applicant's claim 5) perform differently? Note that a new rejection has been added to possibly address this, wherein, it would have been obvious to one having ordinary skill in the art to have made/tried the augment of Kuber comprising any known material in the prosthetic art having predictable results.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 109 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 109 positively claims the acetabular cup which is mounted to the acetabulum of the subject; this positively claims the acetabulum.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 4-6, 14, 15, 27-32, 37-39, and 109 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, "*wherein the augment material is formulated not to transform into scar tissue"* is still ambiguous. The paragraph before claims, "*wherein the augment material is supplemented with at least one of an agent to promote the formation of scar tissue*".

Regarding claims 1, 27 and 29, "*wherein the augment is formulated not to transform into scar tissue*" is indefinite. Note that each claim allows the augment to be a biologically absorbable material. Why does applicant's augment, made from the same material, not transform into scar tissue?

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4-6, 14, 15, 27-32, 37, 109, and 110 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Regarding claim 1, "*wherein the augment is formulated not to transform into scar tissue*" is new matter. Further, the paragraph before claims, "*wherein the augment material is supplemented with at least one of an agent to promote the formation of scar tissue*". The specification does not support a material that does not transform into scar tissue but contains an agent to promote scar tissue.

Regarding claims 27 and 29, "*wherein the augment is formulated not to transform into scar tissue*" is new matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 4-6, 14, 15, 27-32, 37, 109 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kuber (DE 19716051, applicant submitted).

1. (CURRENTLY AMENDED) A prosthetic device for use with a hip replacement prosthesis that includes an acetabular cup assembly to be fastened to a patient's pelvis and a femoral stem to be fastened to the patient's femur, where the femoral stem includes a ball component at its proximal end received within the acetabular cup assembly to form a ball joint type coupling, the prosthetic device comprising:

an acetabular liner B for releasably an acetabular cup permanently mounted to the patient's pelvis (Note that the claim no longer positively claims the mating features and is interpreted as functional language only, however, note figure 4, any of the tab-like elements or figure 3, the indent elements); and

a semiannular augment A to be mounted approximate to a rim of an acetabular assembly liner of a hip replacement prosthesis, wherein the semiannular augment assists in improving stability of a ball joint type coupling by increasing the height of a

portion of the rim of the acetabular liner, at least temporarily, between the acetabular assembly liner and a femoral stem of the hip replacement prosthesis while allowing rotational and angular movement between the acetabular cup assembly and the femoral stem;

the semiannular augment being formed from an augment material comprising at least one of a biologic material, a biologically absorbable material, and a combination of biologic and biologically absorbable materials; and

wherein the augment material is formula not to transform into scar tissue (note Kuber and applicant teach PLLA, see at least applicant's claim 5).

Regarding at least claim 1, however, Kuber fails to teach the augment material is supplemented with at least one of an agent to promote the formation of scar tissue, a clotting agent, and an antibacterial agent. It is would have been obvious to one having ordinary skill in the art to have utilized any of the known biologic materials (bioresorbable or non-bioresorbable) or combinations thereof and to include an agent to promote scar tissue, clotting, and antibacterial agent for their known biocompatibility and characteristic such as preventing a bacterial infection. Kuber teaches the semiannular augment being formed of PLLA. It is well know in the art to form femoral head retaining structures from other materials including non-resorbable material. It would have been obvious to one having ordinary skill in the art to have made/tried the augment of Kuber comprising any known material in the prosthetic art having predictable results.

In the alternative, if Kuber does not teach a liner/cup configuration, under 35 U.S.C. 103(a): Regarding the mating features to releasable engage corresponding mating features of an acetabular cup, these features are well known in the art; see Mikhail (5,549,701) teaching a liner 12 having mating features 34 and 30. Note Mikhail teaches the liner can be implanted into an acetabular cup 14 as shown in figure 1 or directly implanted into the acetabulum as shown in figure 2. It would have been obvious to one having ordinary skill in the art to have used any mating features **and a cup** known in the art such as those taught by Mikhail on/with the plastic liner B of Kuber to anchor the liner in a cup preventing relative motion which produces wear debris.

Regarding claims 2 and 29, see fastener C made of PLLA.

Regarding claims 4 and 30, fastener C is a screw.

Claims 6 and 32 only further defines the ECMs.

Regarding at least claim 14, the screw is integrated.

Regarding at least claim 15, applicant's specification teaches various fastening means including screws; see paragraph 0032 and 4. At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to snap-on retention members. Applicant has not disclosed that said configuration provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with either screws or a snap-on configuration. Therefore, it would have been obvious to one of ordinary skill in the art to modify Kuber to obtain the invention as claimed with expected results.

Regarding claim 37, see reasoning above.

Regarding claim 109, it would have been obvious to one having ordinary skill in the art to have made the augment of Kuber into multiple separate parts or sized smaller such that the surgeon could place the augment(s) only where deemed necessary for the patient introducing less foreign matter into said patients body and require a smaller incision. MPEP 2144 states: The rationale to modify or combine the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law. See MPEP 2144.04 IV (A) Changes in size/proportion and (C) Making Separable.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E. Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

bes

BRUCE SNOW
PRIMARY EXAMINER